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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/660,093	09/11/2003	Kenneth E. Miller	5820.641	5920

30589 7590 12/28/2007
DUNLAP CODDING & ROGERS, P.C.
PO BOX 16370
OKLAHOMA CITY, OK 73113

EXAMINER

SRIVASTAVA, KAILASH C

ART UNIT	PAPER NUMBER
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1657

MAIL DATE	DELIVERY MODE
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12/28/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/660,093	Applicant(s) MILLER, KENNETH E.	
	Examiner Dr. Kailash C. Srivastava	Art Unit 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-11,19 and 21-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-11,19 and 21-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. <u>12/21/2007</u> |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Response and amendment filed 09 October 2007 in response to Office Action mailed 06 June 2007 is acknowledged and entered. The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office action.

Withdrawals of Objections and Rejection based on Applicant's Amendments

2. In view of remarks and amendments filed 09 October 2007, the following objections and rejections in Office Action mailed 06 June 2007 are hereby withdrawn:
 - Objection to each of Claims 7-8 and 22-23 because of missing “, (i.e., a comma)” at Line 1, before the word, “wherein”.
 - Enablement rejection to Claims 1, 3-11, 19 and 21-23 under 35 U.S.C. §112, first paragraph regarding inhibition of glutaminase enzyme production by said step through oral administration of said glutaminase inhibitor.
 - Enablement rejection to Claims 1, 3-11, 19 and 21-23 under 35 U.S.C. §112, first paragraph, regarding alleviating the chronic pain in the peripheral nervous system of an individual via orally administering a glutaminase inhibitor to said individual.
 - Indefiniteness rejection of Claims 3 and 21 under 35 U.S.C. §112, second paragraph, for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
 - Obviousness rejection Claims 1, 3-11, 19 and 21-23 under 35 U.S.C. § 103(a) as obvious over the combined teachings from Rosenberg (U.S. Patent 5,158,976) with evidence provided by Melzack et al. (Pain Mechanisms: A New Theory, Science, Volume 150, Number 3699, 19 November 1965, Pages 971-979) and further in view of Fujimoto et al (U.S. Patent 6,291,523).

Claims Status

3. Claims 2, 12-18 and 20 remain cancelled.
4. Claims 1, 3, 7-8, 19, 21 and 23 have been amended.

5. Claims 1, 3-11, 19 and 21-23 are pending and are examined on merits.

Information Request under 37 C.F.R. §1.105

6. Applicant and the assignee of this application are required under 37 C.F.R. §1.105 to provide the following information that the examiner has determined is reasonably necessary to the examination of this application. This requirement is subject to the provisions of 37 C.F.R. §§1.134, 1.135 and 1.136 and has a shortened statutory period of 2 months. **EXTENSIONS OF THIS TIME PERIOD MAY BE GRANTED UNDER 37 C.F.R. §1.136(a).**

Claim 1 as currently presented lists inhibitors of neurotransmitter synthesis to be selected from the group consisting of a glutamine synthetase inhibitor, a glutamate dehydrogenase inhibitor, a pyruvate carboxylase inhibitor, a glutamine cycle inhibitor, a glial cell tricarboxylic acid cycle inhibitor, and combinations thereof; and

Claim 3 lists at least one inhibitor of neurotransmitter synthesis to be selected from the group consisting of phenyl acetic acid (i.e., PAA), phenylacetyl Coenzyme-A, phenylacetyl Co-A ester, oxamate, methionine-S-sulfoximine (i.e., MSO), phosphinothricin (i.e., PPT), 4-N- hydroxy-L-2,4-diaminobutyric acid (i.e., NH-DABA), Delta-hydroxylysine, bromofuroate, Palmitoyl-Coenzyme-A (i.e., Palmitoyl-Co-A), orthovanadate, vanadyl sulphate, vanadyl acetylacetonate, glutarate, 2-oxoglutarate (i.e., o-ketoglutarate), estrogen, estrogen analogues, pyridine-2,6-dicarboxylic acid, fluoroacetate, fluorocitrate, and combinations thereof.

Since it is not clearly apparent which compound(s) listed in claim 3 correspond to the broad classes of inhibitors of neurotransmitter synthesis listed in claim 1, applicant/assignee is requested to clarify which compound(s) listed in Claim 3 correspond to which inhibitor (e.g., glutamine synthetase inhibitor) listed in Claim 1. Therefore, the examiner is requesting that applicant supply the above requested information of which applicant is aware and upon which applicant based the instant claims for the examiner to consider.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Long*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. §1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. §3.73(b).

8. Claims 1, 3-11, 19 and 21-23 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-2, 4-13 and 15-16 of U.S. Patent No. 7,288,246 B2. Although, conflicting claims are not identical, they are not patentably distinct from each other because Claims 1-2, 4-13 and 15-16 of referenced patent are drawn to a method comprising essentially the same steps for a method to alleviate chronic pain in a subject as claimed in the cited claims of instant application. The instantly claimed Claims 1, 3-11, 19 and 21-23 have a broader scope than Claims 1-2, 4-13 and 15-16 of referenced patent 7,288,246 B2 issued 30 October 2007 to Miller, because instant claim 1 is broader with respect to the inhibitors.

Rejection Under 35 U.S.C. §112, Second Paragraph

9. Claims 1, 3-11, 19 and 21-23 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claims 1 and 19 are unclear with respect to inhibitor of neurotransmitter synthesis, because in each of Claims 1 and 19 are claimed inhibitors of neurotransmitter synthesis as the materials that inhibit enzymes (e.g., glutamine synthetase, glutamate dehydrogenase, pyruvate carboxylase), not the inhibition of the gene/expression responsible for the synthesis of claimed enzymes. Furthermore, inhibition of an enzyme activity is not art-known to be synthesis of the same enzyme because enzyme activity inhibition and enzyme synthesis inhibition are art-known to be two different phenomenon controlled by different parameters.
- Claim 1 is rendered unclear because the correspondence between Claims 1 and 3 that are two differently defined Markush groups is unclear. That is, it is not clear if the Markush group of claim 3 has clear antecedent basis in the Markush group of claim 1.
- Claim 19 is rendered unclear because the correspondence between Claims 19 and 21 that are two differently defined Markush groups is unclear. That is, it is not clear if the Markush group of claim 21 has clear antecedent basis in the Markush group of claim 19.

All other pending claims depend from the rejected claims 1 and 19 respectively and are, therefore, also rejected under 35 U.S.C. §112, second paragraph for the reasons set forth above.


Conclusion

10. For reasons aforementioned, no Claims are allowed.

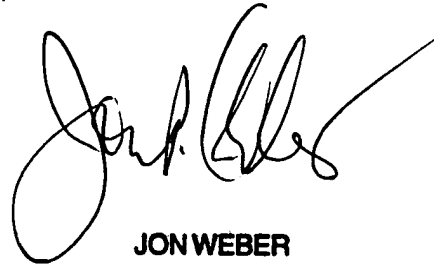
11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached at (571)-272-0925 Monday through Thursday 7:30 A.M. to 6:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


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December 26, 2007


JON WEBER
SUPERVISORY PATENT EXAMINER